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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,072	12/21/2005	Toshihide Kobayashi	P26337	9668

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RESTON, VA 20191

EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/516,072	Applicant(s) KOBAYASHI ET AL.	
	Examiner Paul C. Martin	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 3-21 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

The replacement drawings are acknowledged received on 12/18/06.

The drawings are newly objected to because Figs. 4G-4L should be designated as 4A-4F, Figs. 5N-5T should be designated as 5A-5H, Figs. 7C-7N should be designated as 7A-7L and Figs. 8O-8T should be designated as 8A-8F. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended.

The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The objection to the Specification regarding the use of trademarks therein has been withdrawn due to the Applicant's amendments to the Specification filed 12/18/06.

The disclosure is newly objected to because of the following informalities: The Specification is lacking continuity data (Cross reference to Related Applications) at Pg. 1, Line 1. Appropriate correction is required.

Art Unit: 1657

The disclosure (Brief Description of the Drawings) is objected to because of the following informalities: All of the Figures need further explanation as to what exactly is being described or pictured in each sub-figure set. For example, the brief description for Figure 1 does not reference Figures 1A-1H. Further, Fig. 6 appears to lack identifiers for the two lower figures. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The Claims 3, 4 and 7-21 remain rejected under 35 U.S.C. 112, 1st paragraph for reasons of record set forth in the Action mailed 7/17/06. Applicant's amendment to the Claims do not correct the deficiencies relating to positive method steps in Claim 3. Claims 4 and 7-21 remain rejected as being dependent upon rejected Claim 3.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7-21 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is drawn to a method for detecting cholesterol comprising the steps of contacting a PEG-Chol with a specimen and detecting the presence of cholesterol in the specimen.

Art Unit: 1657

It is unclear how any detection of cholesterol is taking place in this method as 1) the PEG-Chol of Claim 3 contains no detectable label and 2) methods steps relating to any detection and the means for carrying out said detection are lacking in Claim 3 and its dependent Claims. Claims 7-21 are rejected as being dependent upon rejected Claim 3.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "affinity" in claims 1 and 4 is used by the claim to mean "label", while the accepted meaning is "An attraction or force between particles that causes them to combine.." The term is indefinite because the specification does not clearly redefine the term. In fact the Specification appears to refer to affinity substances as labels as well (Pg. 5, Lines 5-9). Claims 12-15 are rejected as being dependent upon rejected Claim 4.

Claim Rejections - 35 USC § 102

The rejection of Claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Ishiwata *et al.* (1997) has been withdrawn due to the Applicant's amendments to the claims filed 12/18/06.

Claims 1, 3-5, 7, 9-12, 14-16, 19 and 20 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Baba *et al.* (2001).

Baba *et al.* teaches a composition comprising a polyethylene glycol cholesteryl ether (PEG-Chol) labeled with the affinity substance biotin (Pg. 509, Column 1, Lines 7-11). The preamble statement that the composition is a cholesterol detection reagent is an intended use and does not materially change the composition as claimed.

Baba *et al.* teaches an *in vitro* method wherein human cancer cells were contacted with PEG-Chol labeled with biotin (bPEG-Chol), followed by incubation with streptavidin-AlexaFluor 488 (fluorescent), the quantitative determination of the amount of bound bPEG-Chol (Pg. 509, Column 1, Lines 15-34) and the qualitative detection of bPEG-Chol binding to cells (Pg. 503, Fig. 2).

Art Unit: 1657

It is inherent in the method of Baba *et al.* that the bPEG-Chol was detectably labeling cell membrane cholesterol. The MPEP states:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-7, 9-12, 14-16 and 19-21 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Baba *et al.* (2001) in view of Wu *et al.* (US 6,005,113).

The teachings of Baba *et al.* were discussed above.

Baba *et al.* does not teach a method wherein the detectable label is digoxigenin.

Wu *et al.* teaches the use of specific binding pairs such as biotin and digoxigenin, when allowed to react with their complementary specific binding pair member for the purposes of detection or quantitation (Column 13, Lines 16-25).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the composition and *in vitro* labeling method comprising a polyethylene glycol cholesteryl ether (PEG-Chol) labeled with biotin as taught by Baba *et al.* above with the use of the digoxigenin as taught by Wu *et al.* because the specific binding pairs would have been recognized by one of ordinary skill in the art as functionally equivalent and the use of alternatives and functional equivalent techniques would have been desirable to those of ordinary skill in the art based upon the economics and availability of compounds and personal preference of the artisan. There would have been a reasonable expectation of success in making this modification because the method of Baba *et al.* taught the use of the biotin-fluorescent streptavidin specific binding pair and Wu *et al.* taught that biotin/digoxigenin were functional equivalents.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Art Unit: 1657

No Claims are allowed.

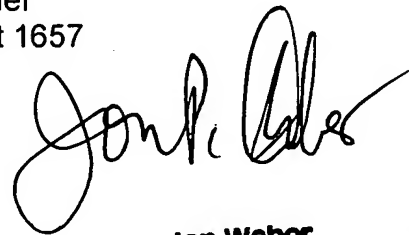
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

3/27/07

A handwritten signature in black ink, appearing to read "Jon Weber", is written over the printed name and title.

Jon Weber
Supervisory Patent Examiner